

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MAGNOLIA MEDICAL TECHNOLOGIES,
INC.,

Plaintiff,

V.

KURIN, INC.,

Defendant.

Civil Action No.: _____

JURY TRIAL DEMANDED

COMPLAINT

Plaintiff Magnolia Medical Technologies, Inc. (“Magnolia”) brings this patent infringement action against Defendant Kurin, Inc. (“Kurin”), and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent No. 9,855,001 (the “’001 patent”) and U.S Patent No. 10,028,689 (the “’689 patent”) (collectively, the “Asserted Patents”) under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

THE PARTIES

2. Plaintiff Magnolia is a Washington corporation with its principal place of business at 200 W. Mercer Street, Suite 500, Seattle, Washington, 98119.

3. Defendant Kurin is a Delaware corporation with its principal place of business in San Diego, CA. Kurin's registered agent, Corporation Service Company, is located at 251 Little Falls Drive, Wilmington, Delaware, 19808.

JURISDICTION AND VENUE

4. Magnolia's claims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* Subject matter jurisdiction exists pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. The Court has both general and specific personal jurisdiction over Kurin consistent with the requirements of the Due Process Clause of the United States Constitution and the Delaware Long Arm Statute. This Court has general personal jurisdiction over Kurin as a Delaware corporation. This Court further has personal jurisdiction because Kurin, directly or through subsidiaries or intermediaries (including distributors, general purchasing organizations, retailers, and others), ships, distributes, offers for sale, sells, and advertises (including the provision of an interactive web page) its products and/or services in the United States and the District of Delaware. Kurin's established distribution networks include warehouses, national distributors, and resellers, and Kurin distributes to national and local purchasing organizations that have member healthcare providers located in this District. By shipping into, selling, offering to sell, and/or using products that infringe Magnolia's Asserted Patents in this District, or by inducing or causing those acts to occur, Kurin has transacted and continues to transact business and perform work and services in this District, has supplied and continues to supply services and things in this District, has caused and continues to cause injury and damages in this District by acts and omissions in this District, and has caused and continues to cause injury and damages in this District by acts or omissions outside of this District while deriving revenue from services or things used or consumed within this District, and will continue to do so unless enjoined by this Court.

6. Venue is proper in this district under 28 U.S.C. § 1400(b) because Kurin, as a Delaware corporation, resides in this district.

THE ASSERTED PATENTS

7. The '001 patent is entitled "Systems and Methods for Parenterally Procuring Bodily-Fluid Samples With Reduced Contamination," and issued on January 2, 2018, to inventor Dr. Richard G. Patton. Magnolia owns the entire right, title, and interest in and to the '001 patent. A true and correct copy of the '001 patent is attached to this Complaint as Exhibit A.

8. The '689 patent is entitled "Systems and Methods for Parenterally Procuring Bodily-Fluid Samples With Reduced Contamination," and issued on July 24, 2018, to inventor Dr. Richard G. Patton. Magnolia owns the entire right, title, and interest in and to the '689 patent. A true and correct copy of the '689 patent is attached to this Complaint as Exhibit B.

THE CONTROVERSY

9. Magnolia was co-founded in 2008 by Dr. Richard G. Patton, a physician, Board-certified pathologist, and pioneer in the areas of clinical microbiology and cytopathology, and Greg Bullington. For decades in active practice, Dr. Patton saw first-hand the problem of false positive test results in blood cultures from patient samples, and the inadequate solutions for reducing those false positives.

10. As part of routine and specific testing procedures, medical professionals draw patient blood for testing, including testing for the presence of a blood-borne infection (such as sepsis). Because sepsis is such a serious condition, a positive result will generally influence clinical decision-making, including the prescribing of antibiotics and additional tests in response.

11. A positive test result can stem from a contaminant, *e.g.*, a contaminant originating from the patient's own skin, rather than venous blood. Such a result is called a "false positive"—meaning that the test indicated the potential presence of organisms causing sepsis, when in fact those organisms were not in the patient's blood. The national average contamination rate for blood

samples has been estimated at 3.5%, which amounts to over one million contaminated blood cultures annually.

12. False positive test results threaten patient care. The antibiotic regimen typically prescribed in response to an initial sepsis diagnosis is robust: many patients experience a negative response to such potent treatments, and the sepsis protocol care path often exposes the patient to the delivery of additional unnecessary care and the meaningful risk of negative health events which could have been avoided if the false positive had not occurred.

13. False positive test results can also significantly increase the cost of medical care. For instance, by one estimate, false positives are responsible for a 20% increase in laboratory costs and a 40% increase in antibiotic charges. (*See Exhibit C, M. Rupp et al., Reduction in Blood Culture Contamination Through Use of Initial Specimen Diversion Device, 65 Clinical Infectious Diseases No. 2, pp. 201–05 (July 15, 2017).*) And a study by the University of Houston determined that a single blood culture contamination event costs the hospital \$4,738. (*See Ex. D, E. Skoglund, et al., Estimated Clinical and Economic Impact Through Use of a Novel Blood Collection Device to Reduce Blood Culture Contamination in the Emergency Department: A Cost-Benefit Analysis, 57 J. Clinical Microbiology No. 1, pp. 1–10 (2019).*)

14. To solve this problem, in 2006, Dr. Patton documented in a patent application his earlier conception of the Initial Specimen Diversion Technique (“ISDT”), which diverts the first portion of blood from the tested sample. In 2010, the Journal of Clinical Microbiology published the results of Dr. Patton’s initial clinical trial conducted using ISDT, which was found to significantly reduce the rate of contaminated blood cultures. (*See Exhibit E, R. Patton et al., Innovation for Reducing Blood Culture Contamination: Initial Specimen Diversion Technique, 48 J. Clinical Microbiology No. 12, pp. 4501–03 (Dec. 2010).*) ISDT has since been recognized as a

“Best Practice” for blood cultures. (*See* Exhibit F, J. Schuur, Blood Cultures: When Do They Help and When Do They Harm? Clinical Decision Making in Emergency Medicine, Mount Sinai, June 2012 at 26, 41.)

15. To bring the benefits of ISDT to patients, Dr. Patton and Magnolia were early movers and innovators in this field. Those efforts have resulted in Magnolia’s patent portfolio and the development of the patented Steripath® devices, end-to-end sterile mechanical apparatuses that clinicians in hospitals can easily use to implement the benefits of ISDT and significantly reduce blood sample contamination. Since its commercial launch in 2014, healthcare providers and researchers around the country have made use of Steripath® to significantly reduce false positive diagnostic test results for sepsis.

16. The clinical value of Magnolia’s innovations and the Steripath® device have been independently validated by third-party peer-reviewed research. Indeed, a study from the University of Nebraska Medical Center found not only that the Steripath® devices led to a 92% reduction in blood culture contamination, but that it could save the Medical Center \$1,800,000 per year by reducing unnecessary extra hospital stays, charges, and antibiotic treatments associates with false positives. (*See* Exhibit C, at 205.) Similarly, researchers from the University of Houston have estimated that the routine use of Steripath® in the emergency department would result in a cost savings of \$79 to \$352 per blood culture collection at baseline contamination rates ranging from 2% to 8%, respectively. (*See* Exhibit D, at 5.)

17. Another multi-center controlled clinical study from Lee Health evaluated the use of the Steripath® device on venipuncture and peripheral IV start blood culture draws in four emergency departments. (*See* Exhibit G, M. Bell, *et al.*, Effectiveness of a Novel Specimen Collection System in Reducing Blood Culture Contamination Rates, 44 Journal of Emergency

Nursing No. 6, pp. 570–575 (Nov. 2018).) This study demonstrated an 83% reduction in blood culture contamination over a seven-month period. (*Id.*) The San Antonio Military Medical Center evaluated the Steripath® device and achieved a 92% reduction in blood culture contamination with a rate of 0.6% when Steripath® was used on both venipuncture and peripheral IV start blood culture draws in the emergency department. (*See* Exhibit H, D. Chang, *et al.*, Impact of Blood Culture Diversion Device and Molecular Pathogen Identification on Vancomycin Use, 2017 Society of Healthcare Epidemiology of America Conference (pending submission for publication); Exhibit I, C. Lanteri, *et al.*, Reduction of Blood Culture Contaminations in the Emergency Department, Department of Defense Healthcare Quality & Safety Awards (2016).)

18. Kurin was founded in late 2015. It markets blood collection sets called the “Kurin Lock” that purport to reduce blood culture contamination. As detailed below, Kurin’s follow-on product, as well as its use, infringe the Asserted Patents.

CLAIMS FOR RELIEF

19. The accused products include, but are not limited to, all configurations of Kurin blood collection sets and/or Kurin Lock technology, including the configurations that Kurin markets as Safety Slide Needle, Push Button Needle, and Peripheral IV (“PIV”) sets (collectively, the “Kurin Accused Products”). On information and belief, the Kurin Accused Products include a Kurin Lock “specimen diversion device” that “enabl[es] clinicians to automatically divert the initial aliquot of blood, which may contain skin microbes, from every draw.” (*See* Exhibit J (<https://www.kurin.com/kurin-lock-specimen-diversion-device/>), at 1.) As detailed below, each element of at least one claim of the Asserted Patents is literally present in the Kurin Accused Products, or is performed by Kurin’s end users as induced by Kurin. To the extent that any element is not literally present or performed, each such element is present or performed under the doctrine of equivalents.

COUNT I
INFRINGEMENT OF THE '001 PATENT

20. Magnolia incorporates the allegations of all the foregoing Paragraphs as if fully restated herein.

21. Among the claims of the '001 patent, claim 1 recites as follows:

An apparatus for obtaining a bodily fluid sample from a patient with reduced contamination, the apparatus comprising:

a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient; and

a diverter having an inlet, a first outlet in fluid communication with the reservoir, and a second outlet, the inlet configured to be fluidically coupled to the patient, the diverter operable in a first operating mode in which a) a subsequent volume of bodily fluid can flow from the inlet to the second outlet, and b) the initial volume of bodily fluid is prevented from flowing to the second outlet,

the diverter configured to transition from the first operating mode to the second operating mode as a result of the initial volume of bodily fluid flowing from the patient and substantial pressure equalization, thereby sequestering in the reservoir contaminants present in the initial volume of bodily fluid, thereby reducing contamination of the subsequent volume of bodily fluid withdrawn from the patient.

22. Kurin directly infringes, and/or induces the infringement of, at least claim 1 of the '001 patent, either literally or under the doctrine of equivalents, by making, using, selling, and/or offering to sell within the United States without authority or license, at least the Kurin Accused Products. Further discovery may reveal additional infringing products.

23. For example, and without limitation, the Kurin Lock is an apparatus for obtaining a bodily fluid sample from a patient with reduced contamination. For example, the Kurin website states that "Kurin is a device designed to contain the initial volume of blood from the venipuncture site, so that resident contaminants within the skin are not transferred into the blood culture sample." (See Exhibit K (<https://www.kurin.com/skin-contaminant-diversion/>), at 2).

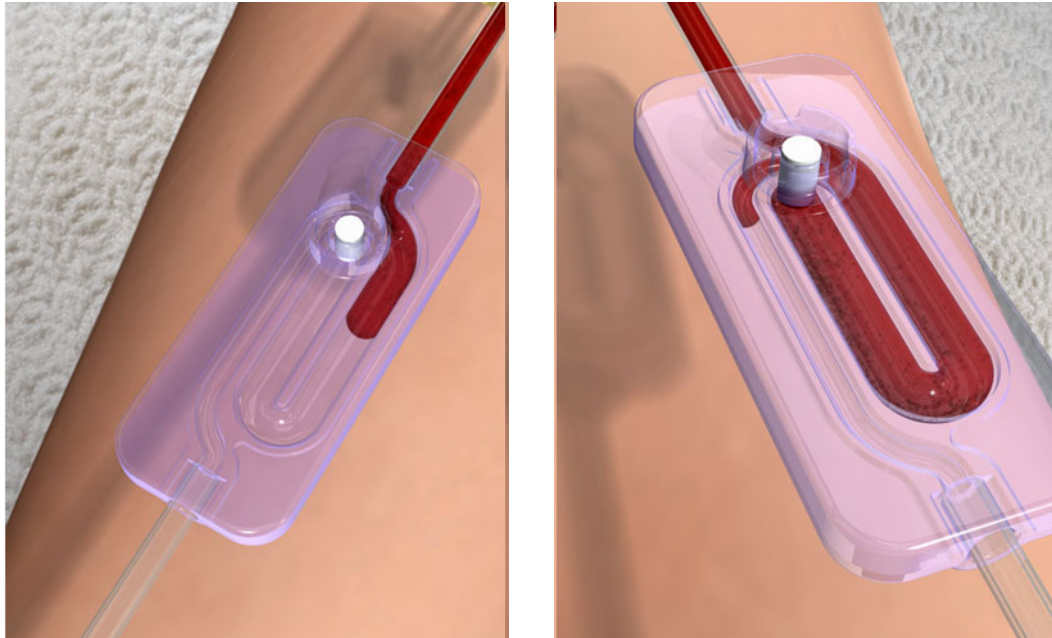
24. The Kurin Lock includes a reservoir configured to receive an initial volume of bodily fluid withdrawn from the patient. For example, the Kurin website states that after “the needle is placed properly within the vein[,] the initial flow of blood—and any contaminants therein—fills a ‘U’ shaped side channel.” (See Exhibit K, at 2.)

25. The Kurin Lock further includes a diverter having an inlet, and the inlet is configured to be fluidically coupled to the patient, as shown below:



(See Exhibit J at 2.)

26. The Kurin Lock further includes a diverter having a first outlet in fluid configuration with the reservoir, and a second outlet. As shown below (right), for example, the first inlet (right) is connected to the “‘U’ shaped side channel” reservoir. (See Exhibit K, at 3–4.) Further, as shown below (left), for example, the Kurin Lock includes a second outlet. (*Id.*)



27. The Kurin Lock further includes a diverter operable in a first operating mode in which an initial volume of bodily fluid can flow from the inlet to the first outlet. For example, the Kurin website states that after the needle is properly placed within the vein, “[t]he initial flow of blood—and any contaminants therein—fills a ‘U’ shaped side channel.” (See Exhibit K, at 2.)

28. The Kurin Lock further includes a diverter operable in a second operating mode in which a) a subsequent volume of bodily fluid can flow from the inlet to the second outlet and b) the initial volume of bodily fluid is prevented from flowing to the second outlet. For example, the Kurin website states that the after the initial flow of blood:

Flow—in or out—of the side channel is stopped, locking the initial blood and contaminants in place.

With the side channel sealed, a small amount of blood will bypass the contents of the side channel, flowing directly into the collection passage. The blood will advance a variable distance before automatically stopping to indicate that the set is ready for collection bottle attachment.

Once attached, the blood flowing into the culture bottle passes directly from the venipuncture, circumventing the potentially contaminated blood sidelined within the Kurin lock.

(See Exhibit K, at 2.)

29. The Kurin Lock further includes a diverter configured to transition from the first operating mode to the second operating mode as a result of the initial volume of bodily fluid flowing from the patient and substantial pressure equalization, thereby sequestering in the reservoir contaminants present in the initial volume of bodily fluid, thereby reducing contamination of the subsequent volume of bodily fluid withdrawn from the patient. For example, the Kurin website states “[t]he initial flow of blood—and any contaminants therein—fills a ‘U’ shaped side channel until it reaches a white porous seal. . . . When in contact with blood, the seal material is activated to lock the channel so that blood cannot exit and air cannot enter. Flow—in or out—of the side channel is stopped, locking the initial blood and contaminants in place. . . . With the side channel sealed, a small amount of blood will bypass the contents of the side channel, flowing directly into the collection passage.” (*See* Exhibit K, at 2.)

30. Kurin has had knowledge of the ’001 patent and that its activities infringe the ’001 patent since at least the date of the filing of the Complaint.

31. Upon information and belief, Kurin had knowledge and notice of the ’001 patent even earlier. At least as early as December 29, 2016, Kurin had knowledge of the 8,197,420 patent, which was cited as prior art by the examiner during prosecution of a patent application assigned to Kurin. The ’420 patent is the parent patent to the ’001 patent. Kurin also cited the ’420 patent in Information Disclosure Statements submitted during prosecution of applications that eventually issued as U.S. patents in at least January 2017. Additionally, Kurin has cited to Magnolia patents in prosecuting its own patents for many years. For example:

- (a) U.S. Patent No. 10,010,282, assigned to Kurin and issued on July 3, 2018, cites to Magnolia’s U.S. Patent Nos. 8,197,420, 8,535,241, 8,864,684, 9,022,951, 9,060,724, 9,204,864, and Magnolia’s U.S. Patent Publication No. 2008/0145933
- (b) U.S. Patent No. 10,143,412, assigned to Kurin and issued on December 4, 2018, cites to Magnolia’s U.S. Patent Nos. 8,197,420,

8,535,241, 8,864,684, 9,022,951, 9,060,724, 9,204,864, and
Magnolia's U.S. Patent Publication Nos. 2008/0145933 and
2013/0317391

32. Therefore based on Kurin's citation of other Magnolia patents and the belief that Kurin was following the development of Magnolia's patent portfolio, Kurin had pre-suit notice of the '001 patent as of January 2, 2018, the date it issued.

33. On information and belief, Kurin has indirectly, and is indirectly, infringing at least claim 1 of the '001 patent in violation of 35 U.S.C. § 271(b), by making, using, offering for sale, and selling at least the Kurin Accused Products in the United States without authority. Kurin induces its customers and/or end-users to infringe one or more claims of the '001 patent at least by encouraging, instructing, and aiding one or more persons in the United States, including but not limited to Kurin employees who test and operate the Kurin Accused Products at the direction of Kurin, to make, use (including testing those devices and methods), sell, or offer to sell one or more of the Kurin Accused Products in a manner that infringes the '001 patent. For example, Kurin provides a video both on its website and on YouTube that instructs physicians or clinicians on how to use the Kurin Accused Products in a manner that infringes exemplary claim 1 of the '001 patent as described above. (*See, e.g.,* <http://www.kurin.com>; <https://www.youtube.com/watch?v=LWuZyhq5XNk>.)

34. Kurin's infringement of the '001 patent has damaged and will continue to damage Magnolia. Magnolia is entitled to recover damages adequate to compensate for Kurin's infringement.

COUNT II **INFRINGEMENT OF THE '689 PATENT**

35. Magnolia incorporates the allegations of all of the foregoing Paragraphs as if fully restated herein.

36. Among the claims of the '689 patent, claim 17 recites as follows:

An apparatus for establishing a sampling flow path substantially free of microbial artifacts between a patient and a sample vessel, the apparatus comprising:

an input tube configured to be fluidically coupled to the patient;

an output tube configured to be fluidically coupled to the sample vessel;

a contaminant reservoir fluidically coupled to the input tube and the output tube; and

a junction disposed between the inlet tube and the output tube and fluidically coupled to the input tube, the output tube, and the contaminant reservoir,

the contaminant reservoir and the junction operable in a first state to allow a first portion of biological fluid to flow into the contaminant reservoir,

the contaminant reservoir and the junction operable in a second state to (a) sequester the first portion of biological fluid in the contaminant reservoir, and (b) to allow a second portion of biological fluid to bypass the contaminant reservoir and to flow to the output tube,

the contaminant reservoir and the junction operable to transition to the second state without manual intervention as a direct result of filling the contaminant reservoir.

37. Kurin directly infringes, and/or induces the infringement of, at least claim 17 of the '689 patent, either literally or under the doctrine of equivalents, by making, using, selling, and/or offering to sell within the United States without authority or license, at least the Kurin Accused Products. Further discovery may reveal additional infringing products.

38. For example, and without limitation, the Kurin Lock is an apparatus for establishing a sampling flow path substantially free of microbial artifacts between a patient and a sample vessel. For example, the Kurin website states that "Kurin is a device designed to contain the initial volume of blood from the venipuncture site, so that resident contaminants within the skin are not

transferred into the blood culture sample.” (See Exhibit K (<https://www.kurin.com/skin-contaminant-diversion/>), at 2).

39. The Kurin Lock includes an input tube configured to be fluidically coupled to the patient, as shown below:



(See Exhibit J, at 2.)

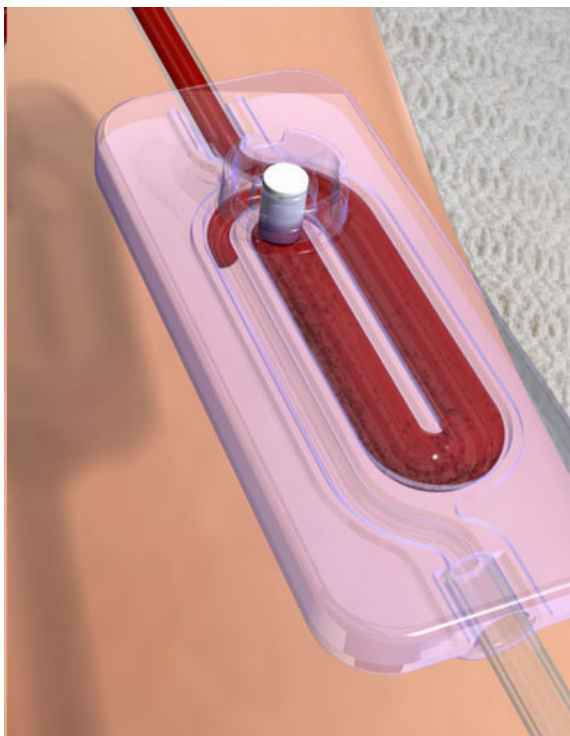
40. The Kurin Lock further includes an output tube configured to be fluidically coupled to the sample vessel, as shown below:



(See Exhibit K, at 5.)

41. The Kurin Lock further includes a contaminant reservoir fluidically coupled to the input tube. For example, the Kurin website states that after “the needle is placed properly within the vein[,] the initial flow of blood—and any contaminants therein—fills a ‘U’ shaped side channel.” (See Exhibit K, at 2.) The “‘U’ shaped” contaminant reservoir is further fluidically coupled to the output tube. For example, the Kurin website states that after the “‘U’ shaped contaminant reservoir is full, “a small amount of blood will bypass the contents of the side channel, flowing directly into the collection passage. . . . [B]lood flowing into the culture bottle passes directly from the venipuncture, circumventing the potentially contaminated blood sidelined within the Kurin lock.” (*Id.*)

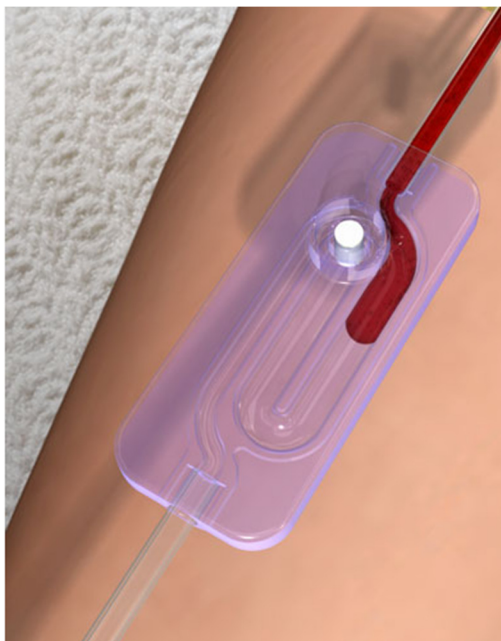
42. The Kurin Lock further includes a junction disposed between the inlet tube and the output tube and fluidically coupled to the input tube, the output tube, and the contaminant reservoir, as shown below:



Approximately 0.15ml of the initial blood flow is captured in the u-shaped Kurin Lock[®] specimen diversion device.

(See Exhibit K, at 4.)

43. The Kurin Lock includes a contaminant reservoir and a junction operable in a first state to allow a first portion of a biological fluid to flow into the contaminant reservoir as shown below:



(See Exhibit K, at 3.) The Kurin website further states that “The initial flow of blood—and any contaminants therein—fills a ‘U’ shaped side channel.” (See Exhibit K, at 2.)

44. The Kurin Lock further includes a contaminant reservoir and a junction operable in a second state to (a) sequester the first portion of biological fluid in the contaminant reservoir, and (b) to allow a second portion of biological fluid to bypass the contaminant reservoir and to flow to the output tube. For example, the Kurin website states that the after the initial flow of blood:

Flow—in or out—of the side channel is stopped, locking the initial blood and contaminants in place.

With the side channel sealed, a small amount of blood will bypass the contents of the side channel, flowing directly into the collection passage. The blood will advance a variable distance before automatically stopping to indicate that the set is ready for collection bottle attachment.

Once attached, the blood flowing into the culture bottle passes directly from the venipuncture, circumventing the potentially contaminated blood sidelined within the Kurin lock.

(See Exhibit K, at 2.)

45. The Kurin Lock further includes a contaminant reservoir and a junction operable to transition to the second state without manual intervention as a direct result of filling the

contaminant reservoir. For example, the Kurin website states “The initial flow of blood—and any contaminants therein—fills a ‘U’ shaped side channel until it reaches a white porous seal. . . . When in contact with blood, the seal material is activated to lock the channel so that blood cannot exit and air cannot enter. Flow—in or out—of the side channel is stopped, locking the initial blood and contaminants in place. With the side channel sealed, a small amount of blood will bypass the contents of the side channel, flowing directly into the collection passage.” (*See* Exhibit K, at 2.)

46. Kurin has had knowledge of the ’689 patent and that its activities infringe the ’689 patent since at least the date of the filing of the Complaint.

47. Upon information and belief, Kurin had knowledge and notice of the ’689 patent even earlier. At least as early as December 29, 2016, Kurin had knowledge of the 8,197,420 patent, which was cited as prior art by the examiner during prosecution of a patent application assigned to Kurin. The ’420 patent is the parent patent to the ’689 patent. Kurin also cited the ’420 patent in Information Disclosure Statements submitted during prosecution of applications that eventually issued as U.S. patents in at least January 2017. Additionally, Kurin has cited to Magnolia patents in prosecuting its own patents for many years. For example:

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48. Therefore based on Kurin’s citation of other Magnolia patents and the belief that Kurin was following the development of Magnolia’s patent portfolio, Kurin had pre-suit notice of the ’689 patent as of July 24, 2018, the date it issued.

49. On information and belief, Kurin has indirectly, and is indirectly infringing at least claim 17 of the '689 patent in violation of 35 U.S.C. § 271(b), by making, using, offering for sale, and selling at least the Kurin Accused Products in the United States without authority. Kurin induces its customers and/or end-users to infringe one or more claims of the '689 patent at least by encouraging, instructing, and aiding one or more persons in the United States, including but not limited to Kurin employees who test and operate the Kurin Accused Products at the direction of Kurin, to make, use (including testing those devices and methods), sell, or offer to sell one or more of the Kurin Accused Products in a manner that infringes the '689 patent. For example, Kurin provides a video both on its website and on YouTube that instructs physicians or clinicians on how to use the Kurin Accused Products in a manner that infringes exemplary claim 17 of the '689 patent as described above. (*See, e.g.,* <http://www.kurin.com>; <https://www.youtube.com/watch?v=LWuZyqh5XNk>.)

50. Kurin's infringement of the '689 patent has damaged and will continue to damage Magnolia. Magnolia is entitled to recover damages adequate to compensate for Kurin's infringement.

JURY DEMAND

51. Magnolia requests a jury trial as to all issues that are triable by a jury in this action.

PRAYER FOR RELIEF

WHEREFORE, Magnolia respectfully requests the following relief:

- (a) A judgment that the '001 patent and the '689 patent are valid and enforceable;
- (b) A judgment that Kurin has infringed, either literally or under the doctrine of equivalents, one or more of the claims of the '001 patent and the '689 patent;

(c) A judgment that awards Magnolia all appropriate damages for the infringement that has occurred, and any continuing or future infringement of the Asserted Patents, up until the date such judgment is entered, including pre- and/or post-judgment interest, costs, and disbursements as justified under 35 U.S.C. § 284, and an accounting adequate to compensate Magnolia for Kurin's infringement;

(d) A judgment that Kurin's infringement of the '001 patent and the '689 patent has been deliberate and willful;

(e) A judgment awarding Magnolia enhanced damages up to three times their amount pursuant to 35 U.S.C. § 284;

(d) A preliminary and/or permanent injunction enjoining Kurin, its officers, agents, servants, employees, and attorneys, and those persons in active concert or participation with them, from further infringement of the '001 patent and the '689 patent;

(e) A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and that Magnolia be awarded its reasonable attorneys' fees against Kurin that Magnolia incurs in prosecuting this action;

(f) An award to Magnolia of costs and expenses that it incurs in prosecuting this action; and

(g) A judgment that Magnolia be awarded such further relief at law or in equity as the Court may deem just and proper.

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Dated: January 16, 2019

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